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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
KRUSE, DAVID H

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 12/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/759,877	NOBLE, STEPHEN W.	
	Examiner	Art Unit	
	David H Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-7,20 and 33* is/are allowed.

6)☒ Claim(s) *8-19,21-32 and 34-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This Office action is in response to the Amendment and Remarks filed 16 October 2002.

2. New claims 33-41 have been added as requested.

3. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and Remarks.

4. The objections to claims 1, 5, 6, 7, 12 and 16 are withdrawn in view of Applicant's amendments and remarks regarding the deposit of biological materials.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

6. Claims 9-11, 13-18, 21, 22-24, 26, 27, 29, 20, 31 and 32 remain rejected and claim 40 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 16 July 2002. Applicant's arguments filed 16 October 2002 have been fully considered but they are not persuasive.

Claims 9, 13, 17, 22, 26 and 30 remain indefinite because the claims do not set forth any positive method steps leading to the maize plant at line 1 of the claims. Hence, it is unclear what the metes and bounds of the claimed methods are. Applicant argues that the techniques described in the present application clearly define and distinctly claim positive method steps for producing maize plants for small or large scale

production (page 11, 4th paragraph of the Remarks). The Examiner responds that this argument equates the disclosure with what is claimed in the instant claims. The Applicant is reminded that limitations within the specification are not read into the claims, although limitations within the claims must be supported by the written description within the specification.

Claims 10, 14, 18, 23, 27 and 31 are indefinite for being dependent upon an indefinite claim. The limitations within said claims do not obviate the indefiniteness of the claim upon which they depend.

Claims 11, 15, 19, 24, 28 and 32 remain indefinite because the phrases "excellent grain yield potential", "strong stalks" and "particularly suited...of the United States", for example, are relative and do not state the metes and bounds of the claimed invention. Applicant argues that the terminology used is well known in the art and commonly used within breeding techniques for hybrid plants. Applicant also argues that the claim indicates that the traits must be originating from 34M94 (page 12, 1st paragraph of the Remarks). The Examiner responds that the instant claims are not limited to hybrid plants. In addition, it remains the Examiner's opinion that the claim limitations are relative. It is clear from the art that the recited traits are not specific to hybrid maize plant 34M94, hence it is unclear what the metes and bounds of the claimed invention are.

Claims 16 and 29 remain indefinite because a hybrid maize plant is not produced by a backcrossing technique. Hence, it is unclear what the metes and bounds of these claims are. Applicant argues that the specification specifically says "recurrent selection

breeding, backcrossing for example, can be used to improve inbred lines in a hybrid...to transfer a specific desirable trait from one inbred or source to an inbred that lacks that trait" (page 13, 2nd paragraph of the Remarks). The Examiner responds that limitations within the specification are not read into the claims, although limitations within the claims must be supported by the written description within the specification as discussed supra. This is not a rejection for enablement. In the Examiner's opinion, the claim limitation "transferred by backcrossing" is contrary to the meaning of the claim, hence the metes and bounds of the claim are unclear. The claim does not stipulate that the "one or more genes" are transferred to a parental line prior to production of the hybrid maize plant 34M94.

Claims 8 and 21 remain indefinite because the plant of claims 2 and 20, respectively, are not male sterile. Applicant's amendments to claims 8 and 21 are noted. However the claims remains indefinite because it is confusing to denote the fertile hybrid maize plant 34M94 as male sterile.

The cancellation of claims 8 and 21, and the submission of the following proposed new claims would obviate this rejection:

-- New claim 42. A method of producing a male sterile corn plant comprising transforming the corn plant of claim 2 with a nucleic acid molecule that confers male sterility.

New claim 43. A male-sterile corn plant produced by the method of claim 42.

New claim 44. A method of producing a male sterile corn plant comprising transforming the corn plant of claim 20 with a nucleic acid molecule that confers male sterility. --

New claim 45. A male-sterile corn plant produced by the method of claim 44. --

At claim 40, the claim is directed to a 34M94 maize plant said plant being produced by a method wherein the exemplified 34M94 maize plant is crossed with a second plant. Clearly the plant at claim 40 cannot be the maize plant of claim 2 designated 34M94 or produced by the method of claim 38, to which the instant claim is directed and only have 50% of it's alleles from the 34M94 maize plant of claim 2. Hence, it is unclear what the metes and bounds of the claimed invention are.

7. Claims 11, 15, 19, 24, 28, 32, 34, 39, 40 and 41 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. At claims 11, 15, 19, 24, 29, 32, 39 and 40, the limitations "wherein said maize plant has derived at least 50% of its ancestral alleles from 34M94" and "deriving at least 50% of its ancestral alleles from 34M94" appear to be new matter, which is not permitted under 37 CFR § 1.53(b) and 35 USC § 132(a). The Examiner notes that Applicant points out at page 14, 4th paragraph, of the response filed 16 October 2002, where the amendment to claims 11, 15, 19, 24, 29, 32 and 39 and new claim 40 is supported in the instant specification. However, the Examiner does not find literal support for this limitation in the specification at the locations designated in Applicant's

response. Hence, it is unclear from the instant specification that Applicant had contemplated such a claim limitation at the time of Applicant's invention.

At claims 34 and 41, the subject matter directed to producing double haploids of the described hybrid maize plant 34M94 appears to be new matter, which is not permitted under 37 CFR § 1.53(b) and 35 USC § 132(a). The Examiner notes that Applicant does not specifically point out in the response filed 16 October 2002, where claims 34 and 41 are supported in the instant specification. Hence, it is unclear from the instant specification that Applicant had contemplated such a claim at the time of Applicant's invention.

8. Claims 11, 12, 15, 16, 19, 24, 25, 28, 29 and 32 remain rejected and claims 8-10, 13, 14, 17, 18, 21-23, 26, 27, 30, 31 and 34-41 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 16 July 2002 for claims 11, 12, 15, 16, 19, 24, 25, 28, 29 and 32. Claims 9, 10, 13, 14, 17, 18, 22, 23, 26, 27, 30 and 31 are now included in the rejection because these claims are broadly drawn to a method of using a multitude of non-exemplified, uncharacterized breeding partners in an unlimited number of crosses, given the open claim language and the failure to specify that an F1 hybrid is produced. Claims 8 and 21 are now included in the rejection because the specification does not describe a plant which is simultaneously male fertile and male sterile. Claims 34 and

35-41 are new claims and will be addressed below. Applicant's arguments filed 16 October 2002 have been fully considered but they are not persuasive.

Applicant argues that they have identified the claimed plants by defining a particular threshold that limits variation and reciting a functional test to identify such plants (paragraph spanning pages 14-15 of the Remarks). Applicant argues that under the written description requirement, Applicant should be allowed to claim the progeny of a cross of maize plants crossed with 34M94 with phenotypic characteristics since they are distinguishing identifying characteristics (page 15, 1st paragraph of the Remarks). Applicant argues that one of ordinary skill in the art is reasonably appraised in knowing that a plant crossed with 34M94 will result in a plant having half of the genetic contribution of 34M94 and must be capable of expressing a combination of at least two phenotypic characteristics of 34M94 (page 16, end of 1st paragraph of the Remarks). This argument is not found to be persuasive because the instant claims are directed to progeny of a hybrid maize plant designated 34M94 that is produced by crossing two inbred parental maize plants designated GE568044 with GE533486. Applicant does not describe any unique feature of said hybrid maize plant that would distinguish it's progeny from say the hybrid maize plant designated 34W67 (U.S. Patent 6,211,445). In addition, because the hybrid maize plant designated 34M94 is a cross between two inbred parental maize plants, the actual genetic complement of each individual hybrid maize plant designated 34M94 could be slightly different from another hybrid maize plant designated 34M94 due to recombination of genetic material. This difference would be amplified in progeny of the hybrid maize plant designated 34M94 due to

crossing over at random loci and segregation. Hence, it is unclear that Applicant can adequately describe a progeny plant produced from the hybrid maize plant designated 34M94 as claimed.

Applicant argues that a person having skill in the art could insert a DNA gene into a selected maize plant and that Applicants have defined transgenes in the present application (page 15, 2nd paragraph of the Remarks). This argument is not found to be fully persuasive because claims 12-15, 16-19 and 25-28 are directed to a transformed hybrid maize plant designated 34M94, and methods of using same, said transformed hybrid maize plant comprising any transgene. Given the breadth of the invention in the instant claims it is unclear if Applicant was in possession of such a broad genus of transgenic hybrid maize plants at the time of the invention because Applicant does not clearly describe what effect all transgenes would have on the hybrid maize plant designated 34M94.

Applicant's argument concerning the test for definiteness on page 16, 2nd paragraph is irrelevant to the instant rejection.

Claims 9, 10, 13, 14, 17, 18, 22, 23, 26, 27, 30 and 31 are now included in the rejection because these claims are broadly drawn to a method of using a multitude of non-exemplified, uncharacterized breeding partners in an unlimited number of crosses, given the open claim language and the failure to specify that an F1 hybrid is produced. Because Applicant has failed to adequately describe the starting materials in the methods of the instant claims, Applicant cannot adequately describe a method of using said starting materials.

Claims 8 and 21 are now included in the rejection because the specification does not describe a plant which is simultaneously male fertile and male sterile.

Claims 34 and 35-41 lack adequate written description because, at claims 34 and 41, Applicant does not describe a method of making a double haploid of the hybrid maize plant designated 34M94. At claims 35-41 Applicant does not adequately describe successive filial generations of the hybrid maize plant designated 34M94 as claimed in claims 36, 37, 39 and 40 and thus does not describe how to practice methods using such filial generations of the hybrid maize plant designated 34M94 in claims 35 and 38. Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

9. Claims 13, 14, 17, 18, 26, 27, 30 and 31 remain rejected and claims 8-11, 12, 15, 16, 19, 21-24, 25, 28, 29, 32 and 34-41 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 16 July 2002 for claims 13, 14, 17, 18, 26, 27, 30 and 31. Claims 8-11, 12, 15, 16, 19, 21-24, 25, 28, 29, 32 34 and 35-41 are now included in the rejection because these claims are broadly drawn to non-exemplified progeny plants, methods of using a multitude of non-exemplified, uncharacterized breeding partners in an unlimited number of crosses, given the open claim language and the failure to specify that an F1 hybrid is produced. Claims 8 and 21 are now included in the rejection because the specification does not describe a plant

which is simultaneously male fertile and male sterile. Claims 34 and 36-41 are new claims. Applicant's arguments filed 16 October 2002 have been fully considered but they are not persuasive.

Applicant argues that the claims have now been amended to properly be drawn from a method thereby obviating this rejection and that Applicant has clearly described and distinctly claimed the subject matter Applicants regard as the invention (page 16, 4th and 5th paragraph of the Remarks). This argument is not found to be persuasive for the reasons given supra for the lack of adequate written description and for the reasons given as follows.

Applicant has provided limited guidance for how to make and use the hybrid maize plant designated 34M94 in the instant specification. The nature of the art at the time of Applicant's invention was such that one of skill in the art could not reasonably predict what the product of a cross between two inbred parental plants would be without a reduction to practice. The art teaches that based on the number of segregating genes, the frequency of occurrence of any individual with a specific genotype is less than 1 in 10,000 and that even if the entire genotype of the parents has been characterized and the desired phenotype is known, only a few if any individuals having the desired genotype may be found in a large F_2 or S_0 population and that typically the genotype of neither the parents nor the desired genotype is known in detail (see Segebart, U.S. Patent 5,304,719, in particular the paragraph spanning columns 2-3). The art also teaches that the number of genes affecting the trait of primary economic importance in maize, grain yield, has been estimated to be in the range of 10-1000 and

that inbred lines which are used as parents for breeding crosses differ in the number and combination of these genes (Segebart, U.S. Patent 5,367,109, column 2, lines 60-64). Segebart ('109) also teaches that one of the largest plant breeding programs in the world does not have a sufficiently large breeding population to be able to rely upon "playing the numbers" to obtain successful research results and that plant breeders use their skills, experience and intuitive ability to select inbreds having the necessary qualities (column 4, 1st and 2nd paragraphs). Hence, given the fact that one of skill in the art cannot reasonably predict the number of genes that affect the trait of grain yield of the parental inbred lines of a hybrid maize plant, it is unclear how one of skill in the art could reasonably predict how to make and use the claimed maize plants and methods of making a maize plant using a second or filial non-exemplified maize plant produced from Applicant's exemplified hybrid maize plant. At claims 11, 15, 19, 24, 28 and 32, the listed 34M94 traits, "excellent grain yield potential", "strong stalks" and "particularly suited...of the United States", for example, are regulated by multiple, non-exemplified genes and that Applicant has failed to teach one of skill in the art how to make the claimed maize plants, even such maize plants having at least 50% of its ancestral alleles from 34M94, because one of skill in the art could not predictably identify such a plant without undue trial and error experimentation. In addition, given the teachings of the prior art it is unclear form the instant specification that one of skill in the art could produce a 34M94 maize plant using the method of claim 38 to derive the 34M94 maize plant of claim 40 without undue trial and error experimentation.

The following amendments would obviate the rejections under 35 USC § 112, first paragraph:

Replace claims 8 and 21 with claims 42-45 as suggested to overcome the rejection under 35 USC § 112, second paragraph.

Cancel claims 9-19, 22-32 and 34-41.

Submit new claims 46-55 below (support for said claims can be found in the specification, pages 45-50).

-- New claim 46. A method of producing an herbicide resistant corn plant comprising transforming the corn plant of claim 2 with a transgene that confers herbicide resistance.

New claim 47. An herbicide resistant corn plant produced by the method of claim 46.

New claim 48. A method of producing an insect resistant corn plant comprising transforming the corn plant of claim 2 with a transgene that confers insect resistance.

New claim 49. An insect resistant corn plant produced by the method of claim 48.

New claim 50. A method of producing a disease resistant corn plant comprising transforming the corn plant of claim 2 with a transgene that confers disease resistance.

New claim 51. A disease resistant corn plant produced by the method of claim 50.

New claim 52. A method of producing a corn plant with decreased phytate content comprising transforming the corn plant of claim 2 with a transgene encoding phytase.

New claim 53. A corn plant with decreased phytate content, produced by the method of claim 52.

New claim 54. A method of producing a corn plant with modified fatty acid or carbohydrate metabolism comprising transforming the corn plant of claim 2 with one or more transgenes encoding a protein selected from the group consisting of stearyl-ACP desaturase, fructosyltransferase, levansucrase, alpha-amylase, invertase, and starch branching enzyme.

New claim 55. A corn plant produced by the method of claim 54. --

Claim Rejections - 35 USC § 102/103

10. Claims 11, 15, 19, 24, 28, 31 and 32 remain rejected and claims 39 and 40 are rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Hoffbeck (US Patent 6,211,445, filed 1 March 1999). This rejection is repeated for the reason of record as set forth in the last Office action mailed 16 July 2002. Applicant's arguments filed 16 October 2002 have been fully considered but they are not persuasive.

The issue of the lack of adequate written description as directed to the instant claims is discussed supra.

Applicant argues that the claimed plant cannot be rendered obvious as it possesses a unique combination of traits, which confers a unique combination of

genetics (page 17, 2nd paragraph of the Remarks). The Examiner withdraws the rejection as it is directed to the hybrid maize plant designated 34M94. The Examiner maintains the instant rejection as it is directed to subsequent progeny plants. Because Applicant is only able to describe the exemplified 34M94 hybrid maize plant based to a limited number of phenotypic traits, the instant claims directed to subsequent progeny plants, even those that have derived at least 50% of their ancestral alleles form 34M94, would have been indistinguishable from that of Hoffbeck. The Examiner notes that even though the claimed plant has 50% of its ancestral alleles from 34M94, the additionally claimed two 34M94 traits are controlled by multiple alleles, many of which would have been common to the 34W67 hybrid maize plant of Hoffbeck.

Applicant argues that the claims do not simply recite traits, but instead recites those specific traits only to the extent that they are "34M94" traits, thereby being derived from the seed/germplasm of 34M94. Applicant also argues that the claim also recites that the claimed plant must have 34M94 as an ancestor further indicating that these traits must originate from the 34M94 plant and not 34W67 (page 19, 3rd paragraph of the Remarks). This argument is not found to be persuasive because the 34W67 hybrid maize plant taught by Hoffbeck is capable of transferring at least two of the same traits as Applicant's 34M94 plant. In addition, because Applicant only describes the 34M94 hybrid maize plant based on phenotypic characteristics, these are the only characteristics one of ordinary skill in the art at the time of Applicant's invention could use to compare progeny of Applicant's 34M94 hybrid maize plant with a progeny of Hoffbeck's 34W67 hybrid maize plant.

Applicant argues that there is no expectation of success that the crossing of the hybrid 34W67 with some yet to be identified plant would yield a plant with two traits enumerated in the claimed invention and at least 50% of its ancestral alleles from 34M94 because that particular plant did not begin with the claimed seed 34M94 which is essential (paragraph spanning pages 18-19 of the Remarks). This argument is not found to be persuasive because of the reasons given in the previous paragraph. In addition, Applicant does not teach 50% of the alleles of the exemplified 34M94 hybrid maize plant by which one of ordinary skill in the art could distinguish progeny of Applicant's 34M94 hybrid maize plant with a progeny of Hoffbeck's 34W67 hybrid maize plant.

Applicant argues that similarities in phenotype between two varieties is not the same as saying that the two varieties have the same morphological and physiological characteristics as a whole, or that one is an obvious variant of the other. Applicant also argues that similarity in phenotype does not mean that the two varieties will perform similarly, particularly in a breeding program (paragraph spanning pages 19-20 of the Remarks). The Examiner responds that the Examiner does not consider the exemplified 34M94 hybrid maize plant of the instant invention to be anticipated or obvious in view of Hoffbeck's 34W67 hybrid maize plant. The Examiner has rejected progeny plants of Applicant's 34M94 hybrid maize plant as being indistinguishable from progeny plant of Hoffbeck's 34W67 hybrid maize plant based on phenotypic distinctions.

Applicant argues that Hybrid 34W67 does not exhibit the same characteristic as 34M94 (page 20, 2nd paragraph to page 21, 1st paragraph of the Remarks). This

argument is not found to be persuasive, because the instant claims are directed to a maize plant expressing "at least two 34M94 traits", while the 34W67 hybrid maize plant inherently discloses such relative traits as "excellent grain yield potential", "particularly suited to the Central Corn Belt region of the United States" and "a relative maturity of approximately 109 based on the Comparative Relative Maturity Rating System for harvest moisture of grain" and thus such traits are not unique identifying traits for hybrid maize 34M94. In addition, given the fact that the 34W67 hybrid maize plant of Hoffbeck is capable of transferring said relative traits, and that these same traits are also affected by the crossing partner, Applicant has failed to adequately distinguish the claimed maize plant from progeny of the 34W67 maize plant of the prior art.

Conclusion

11. This Office action is non-final.

12. Claims 1-7, 20 and 33 are allowed.

13. Claims 8-19, 21-32 and 34-41 are rejected.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

1638

David H. Kruse, Ph.D.
23 December 2002